

510(K) SUMMARY

Submitter: Medos International Sàrl
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Contact Person: Eugene Bang
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Date Prepared: September 16, 2011

Trade Name: DePuy Pulse Anterior Cervical Plate System

Device Class: Class II

Product Code(s): KWQ

Common Name: Appliance, Fixation, Spinal Intervertebral Body

Classification Name: Spinal Intervertebral Body Fixation Orthosis

Regulation Number: 888.3060

Predicate Devices: Skyline Anterior Cervical Plate System – K103491
Slim-Loc Anterior Cervical Plate System – K013877
Uniplate Anterior Cervical Plate System – K082273

Device Description: The DePuy Pulse Anterior Cervical Plate System is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping bone screws using an anterior approach. The DePuy Pulse Anterior Cervical Plate System consists of an assortment of implantable titanium alloy plates and screws in various sizes.

The DePuy Pulse Anterior Cervical Plate System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

Indications: The DePuy Pulse Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to T1 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

Materials: Manufactured from ASTM F-136 implant grade titanium alloy.

Comparison to

Predicate Device: The substantial equivalence of the subject device to the predicates identified above is based upon the equivalence of intended use, design (fundamental scientific technology), materials, manufacturing methods, performance, sterility, biocompatibility, safety and packaging design.

Non-clinical Test

Summary: The following mechanical tests were conducted:

- Static compression bending testing in accordance with ASTM F-1717 *Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Mode*. The acceptance criteria was/were met.
- Static torsion testing in accordance with ASTM F-1717 *Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Mode*. The acceptance criteria was/were met.
- Dynamic compression bending testing in accordance with ASTM F-1717 *Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Mode*. The acceptance criteria was/were met.

Clinical Test

Summary: No clinical tests were performed.

Conclusion: Based on the predicate comparison and testing, the subject device DePuy Pulse Anterior Cervical Plate System is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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Medos International, Sarl
% DePuy Spine, Inc.
Mr. Eugene Bang
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K112724
Trade/Device Name: DePuy Pulse Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 16, 2011
Received: September 19, 2011

Dear Mr. Bang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

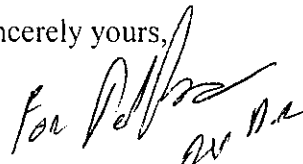
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "For Melkerson" with a stylized flourish.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K112724

Device Name: DePuy Pulse Anterior Cervical Plate System

Indications For Use:

The DePuy Pulse Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to T1 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

Prescription Use X

AND/OR


Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112724